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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	08/971,791
Filing Date	November 17, 1997
First Named Inventor	David A Edwards
Group Art Unit	1616
Examiner Name	K. Shelbourne
Attorney Docket Number	MIT 7513/7804

Sheet 1 of 16

U.S. PATENT DOCUMENTS

Examiner's Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
KES	-	2,470,296		Fields	5/17/49	Class / Subclass 427/213.31
	-	2,533,065		Taplin, et al	3/8/47	424/497
	-	2,992,645		Fowler	7/18/61	128/203.21
		3,781,230		Vassiliades, et al	12/25/73	206/387.1
		3,957,965		Hartley, et al.	05 03/18/76	424/452
		4,009,280		Macarthur, et al.	02/22/77	514/456
		4,089,800		Temple	05 04/16/78	427/213.31
		4,161,516		Bell	07/17/79	424/451
		4,173,488		Vassiliades, et al.	11/06/79	106/216.1
		4,272,398		Jaffe	06/09/81	427/213.31
		4,352,883		Lim	10/05/82	435/178
		4,391,909		Lim	07/05/83	435/1.1
		4,466,442		Hilman, et al.	08/21/84	600/431
		4,524,769		Wetterlin	06/25/85	128/203.15
		4,572,203		Feinstein	02/25/86	424/9.52
		4,590,206		Forrester, et al.	05/20/86	514/456
		4,615,697		Robinson	10/07/86	424/428
		4,679,555		Sackner	07/14/87	128/203.15
		4,741,872		De Luca, et al.	05 03/03/88	264/4.7
		4,743,545		Torobin	05/10/88	435/41
		4,774,958		Feinstein	10/04/88	424/9.52
KES		4,789,550		Hommel, et al.	12/06/88	424/493
		4,818,542		DeLuca, et al.	04/04/89	424/491
		4,847,091		Illum	07/11/89	424/455

Examiner's Signature	Shelbourne	Date Considered	6/14/99
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KES		4,855,144		Leong, et al.	08/08/89	Class / Subclass 424 / 487
		4,857,311		Domb, et al.	08/15/89	514 / 772.3
		4,861,627		Mathiowitz, et al	08/29/89	427 / 213.31
		4,865,789		Castro, et al.	09/12/89	264 / 1122
		4,904,479		Illum.	02/27/90	424 / 490
		4,917,119		Potter, et al.	04/17/90	131 / 273
		4,976,968		Steiner	12/11/90	424 / 491
		4,994,281		Muranishi, et al.	02/19/91	424 / 497
		5,033,463		Cocozza	07/23/91	128 / 203.21
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		5,069,936		Yen	12/03/91	427 / 213.33
		5,075,109		Tice, et al.	12/24/91	424 / 193.1
		5,100,669		Hyon, et al.	03/31/92	424 / 426
		5,123,414		Unger	06/23/92	600 / 431
		5,160,745		DeLuca, et al.	11/03/92	424 / 487
		5,169,871		Hughes, et al.	12/08/92	521 / 64
		5,195,520		Schlief, et al.	03/23/93	600 / 438
		5,204,108		Illum	04/20/93	424 / 434
		5,204,113		Hartley, et al.	04/20/93	424 / 454
		5,260,306		Boardman, et al.	11/09/93	514 / 291
		5,271,961		Mathiowitz, et al.	12/21/93	427 / 213.31
		5,327,883		Williams, et al.	07/12/94	128 / 203.12
		5,334,381		Unger	08/02/94	424 / 9.51
KES		5,352,435		Unger	10/04/94	424 / 9.51

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KES		5,384,133		Boyes, et al.	01/24/95	Class/Subclass 341/22
		5,393,524		Quay	02/28/95	424/19,52
		5,407,609		Tice, et al:	04/18/95	264/4.6
		5,456,917		Wise, et al.	10/10/95	424/426
		5,478,578		Arnold, et al	12/26/95	424/499
		5,482,946		Clark, et al.	01/09/96	514/291
		5,518,709		Sutton,, et al.	04/21/96	424/19,52
		5,607,695		Ek, et al.	03/04/97	424/468

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Examiner's Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
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KES			0 072 048	EPA		02/16/83	Class/Subclass	
			0 213 303	EPA		06/23/86		
			0 257 915	EP		03/02/88		
			0 324 938	EPA		07/26/89		
			0 458 745	EPA		05/14/91		
			0 335 133	EP		10/04/89		
			1 288 583	GB		11/17/69		
			WO 80/02365	PCT WO		11/13/80		
			WO 88/04556	PCT WO		06/30/88		
			WO 88/09163	PCT WO		12/01/88		
KES			WO 91/04732	PCT WO		04/18/91		

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		Examiner Name	K. Shelbourne		
Sheet	5	of	16	Attorney Docket Number	MIT 7513/7804

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
KES		Adjei and Garren, "Pulmonary Delivery of Peptide Drugs: Effect of Particle Size on Bioavailability of Leuprolide Acetate in Healthy Male Volunteers," <u>J. Pharm. Res.</u> , 7(6): 565-569 (1990).	
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		Brown, et al. "Propellant-driven aerosols of functional proteins as potential therapeutic agents in the respiratory tract" <u>Immunopharmacology</u> 28:241-257 (1994)	
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Examiner's Signature	She lborne		Date Considered 6/14/99

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		Attorney Docket Number	MIT 7513/7804

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KES		Carroll, et al. "Gelatin Encapsulated Nitrogen Microbubbles as Ultrasonic Contrast Agents" <u>Investigative Radiology</u> 15: 260-266 (1980).	
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KES		Darquenne, et al. "Two and three-dimensional simulations of aerosol transport and deposition in alveolar zone of human lung". Journal of Applied Physiology Davies et al., "Breathing of half-micron aerosols. I. Experimental," <u>J. Appl. Physiol.</u> 32:591-600 (1972).	
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		Edwards, et al. "Large Porous Particles for Pulmonary Drug Delivery" <u>Science</u> , 276: 1868-71 (1997).		
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KES		French, Edwards, and Niven, "The influence of formulation on emission, deaggregation and deposition of dry powders for inhalation," <i>J. Aerosol Sci.</i> , 27: 769-783 (1996).	
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		Gonda, "Targeting by deposition," in <i>Pharmaceutical Inhalation Aerosol Technology</i> (ed. A.J. Hickey), Marcel Dekkar Inc., New York, 1992.	
		Gurney, et al. Bioadhesive intraoral release systems: design, testing and analysis" <i>Biomaterials</i> 5: 336-340 (1984)	
		Heyder et al., "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 micrometers," <i>J. Aerosol Sci.</i> , 17: 811-825 (1986).	
KES		Heyder and Rudolf, "Mathematical models of particle deposition in the human respiratory tract," <i>J. Aerosol Sci.</i> , 15:697-707 (1984).	
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01/11/99 156 PTO		Application Number	08/971,791		
		Filing Date	November 17, 1997		
		First Named Inventor	David A Edwards		
		Group Art Unit	1615		
		Examiner Name	K. Shelbourne		
Sheet	9	of	16	Attorney Docket Number	MIT 7513/7804

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KES		Heyder et al., "Total Deposition of Aerosol Particles in the Human Respiratory Tract for Nose and Mouth Breathing," <u>J. Aerosol Sci.</u> , 6:311-328 (1975).	
		Hickey et al., "Use of particle morphology to influence the delivery of drugs from dry powder aerosols," <u>J. Biopharmaceutical Sci.</u> , 2(1/2):107-113 (1992).	
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KE5		Kobayashi, S., et al., "Pulmonary Delivery of Salmon Calcitonin Dry Powders Containing Absorption Enhancers in Rats" <i>Pharm. Res.</i> , 13(1): 80-83 (1996)	
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KES		LeCorre et al., Preparation and characterization of bupivacaine-loaded polylactide and polylactide-co-glycolide microspheres," <u>Int. J. Pharmaceutics</u> , 107:41-49 (1994).	
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		Mathiowitz et al., "Morphology of Polyanhydride Microsphere Delivery Systems" <u>Scanning Microscopy</u> 4: 329-340 (1990)	
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		Filing Date	November 17, 1997		
		First Named Inventor	David A Edwards		
		Group Art Unit	1616		
		Examiner Name	K. Shelbourne		
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KES		Menache, et al. "Particle Inhalability Curves for Humans and Small Laboratory Animals" <u>Annals of Occupational Hygiene</u> 39(3): 317-328 (1995).	
		Moren, "Aerosol dosage forms and formulations," in: <u>Aerosols in Medicine. Principles, Diagnosis and Therapy</u> , Moren, et al., Eds, Elsevier, Amsterdam, 1985.	
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KES		Ogiwara, "Clearance and Maximum removal rate of Liposomes in Normal and Impaired Liver of Rat" <u>Gastroenterologia Japonica</u> 19(1) 34-40 (1984).	
		Okumura et al., "Intratracheal delivery of insulin. Absorption from solution and aerosol by rat lung," <u>Int. J. Pharmaceutics</u> , 88:63-73 (1992).	
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		* Phalen, <u>Inhalation Studies: Foundations and Techniques</u> . CRC Press (Boca Rotan, FI), 1984.	
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		Ruffin et al., "The Preferential Deposition of Inhaled Isoproterenol and Propanolol in Asthmatic Patients," <u>Chest</u> 80:904-907 (1986).	
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	Taburet, et al. "Pharmacokinetic Optimisation of Asthma Treatment" <u>Clin. Pharmacokinet.</u> 26(5): 396-418 (1994)		
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		Turner, J. and S. Hering, "Greased and oiled substrates as bounce-free impaction surfaces," <u>J. Aerosol Sci.</u> , 18: 215-224 (1987).	
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Examiner's Signature	Shelbourne		6/14/99

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		Application Number	08/971,791		
		Filing Date	November 17, 1997		
		First Named Inventor	David A Edwards		
		Group Art Unit	1615		
		Examiner Name	K. Shelbourne		
Sheet	16	of	16	Attorney Docket Number	MIT 7513/7804

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
KES		Zanen et al., "The optimal particle size for parasympatholytic aerosols in mild asthmatics" <u>Int. J. Pharm.</u> , 114:111-115 (1995).	
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KES		Zeng et al., "The controlled delivery of drugs to the lung," <u>Int. J. Pharm.</u> , 124:149-164 (1995).	
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